

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----X
MERCK EPROVA AG and MERCK KGaA,

Plaintiffs,

- against -

PROTHERA, INC.,

Defendant.
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08 Civ. 35 (RMB) (JCF)

ORDER

I. Introduction

On January 3, 2008, Merck Eprova AG and Merck KGaA (collectively, “Merck” or “Plaintiffs”) filed a complaint against ProThera, Inc. (“ProThera” or “Defendant”) asserting claims of false advertising, trademark infringement, unfair competition, and trademark dilution under the Lanham Act, 15 U.S.C. §§ 1114 and 1125; a claim of unfair competition under New York State common law; and claims of deceptive trade practices, false advertising, and trademark dilution under New York General Business Law §§ 349, 350, and 360. (See Compl., dated Jan. 3, 2008 (“Compl.”), ¶ 1.) Plaintiffs allege that they are the holders of trademarks consisting of the term “METAFOLIN,” a dietary ingredient containing L-5-methyltetrahydrofolic acid (“L-5-MTHF”), and that Defendant sells dietary supplements “which it has falsely labeled, and continues to falsely label, as containing . . . pure L-5-MTHF.” (Compl. ¶¶ 8–9, 19, 34.) Plaintiff seeks injunctive relief, damages, attorneys’ fees, and costs. (See Compl. ¶ 1.)

On June 1, 2010, Defendant moved for partial summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure (“Fed. R. Civ. P.”) seeking dismissal (only) of Plaintiffs’ false advertising claims under the Lanham Act and the New York General Business Law. (See

Mem. of Law in Supp. of Def.'s Partial Mot. for Summ. J., dated June 1, 2010 ("Mot."), at 1.) Defendant argues, among other things, that: (1) Plaintiffs' false advertising claims are "a poorly disguised attempt to use a Lanham Act claim" to enforce the terms of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., which "creates no private cause of action and can only be enforced by" the Food and Drug Administration ("FDA"); and (2) in the alternative, Plaintiffs' claims "fail substantively [because] Merck cannot satisfy its burden of proving that ProThera's labeling is either 'literally false' or 'implicitly false'" (Mot. at 1–2.)

On June 22, 2010, Plaintiff filed an opposition arguing, among other things, that: (1) "courts have routinely held that Lanham Act claims such as Merck's, which involve no interpretation or application of the FDCA, are not precluded"; and (2) ProThera's use of the term L-5-MTHF on its product labels and advertising is literally false because it "conveys that ProThera's products use . . . pure [L-5-MTHF], when they do not," and "Merck has adduced evidence of actual confusion by consumers to prove implied falsity." (Pls.' Opp'n to Def.'s Mot. for Partial Summ. J., dated June 22, 2010 ("Opp'n"), at 3, 18, 24.)

On July 13, 2010, Defendant filed a reply. On July 20, 2010, Plaintiffs filed a surreply. And, on August 3, 2010, Defendant filed a further reply. (See Reply Mem. of Law in Supp. of Def.'s Mot. for Partial Summ. J., dated July 13, 2010 ("Def.'s Reply"); Pls.' Surreply in Opp'n to Def.'s Mot. for Partial Summ. J., dated July 20, 2010 ("Pls.' Surreply"); Def.'s Reply to Pls.' Surreply, dated Aug. 3, 2010 ("Def.'s Surreply").)

On September 20, 2010 the Court heard oral argument. (See Tr. of Proceedings, dated Sept. 20, 2010 ("Hr'g Tr.").)

For the reasons set forth below, Defendant's motion for partial summary judgment is denied.

II. Background

ProThera is a Nevada corporation which sells dietary supplements. Merck “provides active pharmaceutical and dietary ingredients” to companies such as ProThera. (See Def.’s Statement of Undisputed Facts Pursuant to Rule 56.1, dated June 1, 2010 (“Def. 56.1”), ¶¶ 1–5; Pls.’ Response to Def.’s Statement of Material Facts Pursuant to Rule 56.1, dated June 22, 2010 (“Pls. 56.1”), ¶¶ 1–5.)

At issue is ProThera’s advertising of its dietary supplements containing synthetic forms of folate (a type of vitamin-B). (See Def. 56.1 ¶ 8; Pls. 56.1 ¶ 8.) From approximately July 2006 to approximately January 2008, ProThera sold dietary supplements which contained folate in a form known as D,L-5-methyltetrahydrofolate (“D,L-5-MTHF”), a roughly equal mixture of L-5-MTHF and D-5-methyltetrahydrofolate (“D-5-MTHF”). (See Def. 56.1 ¶¶ 13, 34; Pls. 56.1 ¶¶ 13, 34.) ProThera “state[d] on its labels the quantity of [L-5-MTHF] that was available in each tablet or capsule” of dietary supplement, and that “represented approximately half of the amount of” D,L-5-MTHF present in each tablet or capsule.¹ (Def. 56.1 ¶ 28; Pls. 56.1 ¶ 28; see Def. 56.1 ¶ 34; Pls. 56.1 ¶ 34; Decl. of Janet Ralston, dated May 31, 2010 (“Ralston Decl.”), ¶ 14; see also Def. 56.1 ¶¶ 6–7 (“ProThera currently manufactures and distributes over 200 different dietary supplement products. Approximately 20 to 30 . . . include folate as a dietary ingredient.”).)

Plaintiffs notified ProThera that they objected to ProThera’s advertising and contended that the labeling “creates [an] impression to consumers and healthcare professionals” that

¹ According to ProThera, “[i]n order to deliver the amount of the active [L-5-MTHF] stated on its product labels, ProThera includes slightly more than double [that] amount of [D,L-5-MTHF] in its dietary supplement products. For example, in order to deliver the stated amount of [L-5-MTHF] in a product labeled as providing 1000 micrograms (mcg) or 1 milligram (mg) of folate, each tablet or capsule contains slightly more than 2000 mcg or 2 mg of [D,L-5-MTHF].” (Def. 56.1 ¶ 25.)

ProThera's supplements contained pure L-5-MTHF.² (Pls. 56.1 ¶ 43; see Def. 56.1 ¶¶ 30, 43; see also Decl. of Benjamin Sahl, dated June 1, 2010 ("Sahl Decl."), Ex. C (Expert Report of Elizabeth J. Campbell, dated Feb. 20, 2009 ("Campbell Report")), ¶ 85 ("A health professional who sought the substantially pure [L-5-MTHF] as a folate supplement instead of [D,L-5-MTHF] would be misled by the ProThera labels . . . because nothing in these labels indicate[s] that the folate source declared as [L-5-MTHF] is actually the . . . mixture [D,L-5-MTHF]."); Decl. of Natalie C. Clayton, dated June 22, 2010 ("Clayton Decl."), Ex. 6 (Dep. of Claire Kruger, Ph.D., dated Jan. 28, 2010 ("Kruger Dep.")), at 186:19–187:1 ("Q. [I]f a person was interested in avoiding [D-5-MTHF], does the ProThera label enable them to avoid [it]? A. No. One could not tell how much [D-5-MTHF] is in there by what's on the label.")) Plaintiffs also claim that there exists "an industry-recognized standard of . . . purity for the L-5-MTHF in [a] product[,], namely that the product contains no more than 1.0% D-5-MTHF relative to L-5-MTHF," and that "ProThera has misused the term 'L-5-MTHF' on ProThera's product labels and advertising." (Merck's Supplemental Statement of Material Facts, dated June 22, 2010, ¶ 16 (quoting Clayton Decl. Ex. 24 (Merck's Response to ProThera's Informal Requests for Admission, undated), ¶ 7); see also Ralston Decl. Exs. A–H (ProThera product labels, dated Sept. 2006–Apr. 2010); Decl. of Victoria E. Spataro, dated July 20, 2010 ("Spataro Decl."), Ex. 2 (E-mail from Janet Ralston to Candi Menke, dated July 26, 2006) ("Attached is a notice to be used for informing customers . . . of the name change from Metafolin to MethylFolate. . . . Each Vcaps™ vegetarian capsule of MethylFolate contains 1,000 mcg (1 mg) of folate as [L-5-MTHF]."))

² Plaintiffs allege in their Complaint that they notified Defendant of their objection to Defendant's labeling by email, dated February 14, 2007, and by letter, dated October 8, 2007. (See Compl. ¶¶ 41–42.) In its Answer and Counterclaim ("Answer"), Defendant denies Plaintiffs' allegations. (See Answer, dated Mar. 3, 2008, ¶¶ 41–42.) In their competing Rule 56.1 statements, the parties agree that "Merck objected to ProThera's labeling," but provide no further information. (See Def. 56.1 ¶ 30; Pls. 56.1 ¶ 30.)

According to Plaintiffs, the presence of D-5-MTHF (in D,L-5-MTHF) “may inhibit the uptake and transfer of” L-5-MTHF and, therefore, products which contain both D-5-MTHF and L-5-MTHF – such as Defendants’ products MethylFolate, MultiThera 1, VitaPrime, Vcaps, and Thera-B – are different from (and less desirable than) those which contain pure or nearly pure L-5-MTHF. (Pls. 56.1 ¶ 16 (citing Clayton Decl. Ex. 4 (Expert Report of Dr. Jesse F. Gregory III, Ph.D., dated Feb. 19, 2009 (“Gregory Report”)), ¶¶ 59–66, 68–69 (“Because of the vital role of adequate folate nutrition for cellular growth and cell division, neurological function, and fetal development, it is my opinion that [D-5-MTHF] is not inert and that avoiding it is prudent. Based on the above, it is also my opinion the L-5-MTHF is preferable to [D,L-5-MTHF].”))).) Defendant’s President and CEO, Dennis Meiss, contends that the D-5-MTHF in D,L-5-MTHF “is biologically inactive or inert and is excreted from the body” and thus does not interfere with the role of L-5-MTHF. (Def. 56.1 ¶ 16 (quoting Decl. of Dennis Meiss, dated May 31, 2010 (“Meiss Decl.”), ¶ 17; see also Sahl Decl. Ex. K (Dep. of Harold O. Koch, Jr., dated Apr. 9, 2009 (“Koch Tr.”)), at 193:9-17, 276:2-12).)

III. Legal Standard

Summary judgment is appropriate “if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The Court must view all evidence “in the light most favorable to the non-moving party and draw all reasonable inferences in its favor,” and may grant summary judgment only when no reasonable trier of fact could find in favor of the nonmoving party. Mylan Pharms., Inc. v. Proctor & Gamble Co., 443 F. Supp. 2d 453, 458 (S.D.N.Y. 2006). “[T]he trial court’s task at the summary judgment motion stage . . . is confined . . . to issue-finding; it does not extend to issue-

resolution.” Gallo v. Prudential Residential Servs., Ltd. P’ship, 22 F.3d 1219, 1224 (2d Cir. 1994).

While the FDCA “can only be enforced by the FDA or the Department of Justice, . . . the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act.” Pom Wonderful LLC v. Ocean Spray Cranberries (“Ocean Spray”), 642 F. Supp. 2d 1112, 1118 (C.D. Cal. 2009) (quoting Mut. Pharm. Co. v. Ivax Pharms., Inc., 459 F. Supp. 2d 925, 932–35 (C.D. Cal. 2006)). The issue in determining whether a Lanham Act claim is precluded by the FDCA is “whether the false advertising involves a fact that can be easily verified, without requiring the truth of the fact to be determined by the FDA.” Id.

To establish false advertising under the Lanham Act, “the plaintiff must demonstrate that the message in the challenged advertisement is false. Falsity may be established by proving that (1) the advertising is literally false as a factual matter, or (2) although the advertisement is literally true, it is likely to deceive or confuse consumers.” Lipton v. Nature Co., 71 F.3d 464, 474 (2d Cir. 1995). The federal standards applicable to false advertising claims are substantially similar to the standards applicable to claims brought under §§ 349 and 350 of the New York General Business Law. See Merck & Co., Inc. v. Mediplan Health Consulting, Inc., 425 F. Supp. 2d 402, 410 & n.6 (S.D.N.Y. 2006).

IV. Analysis

No Preclusion

Defendant argues, among other things, that the Complaint, “taken at face value, . . . improperly calls for interpretation of FDA labeling requirements and enforcement of the FDCA.”

(Mot. at 13.) Plaintiffs respond, among other things, that “no direct application or interpretation of the FDCA or FDA regulations is needed.” (Opp’n at 8 (citation omitted).)

Plaintiffs’ Lanham Act claims are not precluded by the FDCA. See Ocean Spray, 642 F. Supp. 2d at 1120; PediaMed Pharm., Inc. v. Breckenridge Pharm., Inc., 419 F. Supp. 2d 715, 726 (D. Md. 2006). “A plaintiff may bring a Lanham Act cause of action for affirmatively misrepresenting facts, even if the facts may be governed by FDA regulations,” Summit Tech., Inc. v. High-Line Med. Instruments Co., 922 F. Supp. 299, 307 (C.D. Cal. 1996), provided that the facts “can be ‘easily verified’ without requiring the truth of the fact to be determined by the FDA.” Ocean Spray, 642 F. Supp. 2d at 1118; see also Healthpoint, Ltd. v. Allan Pharm., LLC, No. SA-07-CA-0526, 2008 WL 728333, at *16 (W.D. Tex. Mar. 18, 2008).

Plaintiffs do not claim that Defendant has violated an FDA regulation or FDCA provision, see Healthpoint Ltd., 2008 WL 728333, at *16, and Plaintiffs “do[] not rely extensively on the FDCA or FDA regulations in support of [their] Lanham Act claims [or] require the Court to interpret or apply any provision of the FDCA or any FDA regulation.” Sciele Pharma, Inc. v. Brookstone Pharm., LLC, No. 09 Civ. 3283, slip op. at 11 (N.D. Ga. June 23, 2010); see also Ocean Spray, 642 F. Supp. 2d at 1118. Rather, Plaintiffs plainly allege that Defendant’s advertising of products which contained D,L-5-MTHF amounted to false advertising under the Lanham Act. (See Compl. ¶¶ 34, 40–53); see also Sciele Pharma, slip op. at 11 (“According to plaintiff, the definition of L-MTHF, and its distinction from D,L-MTHF, is well-established in science and well-accepted in the market.”). Plaintiffs request a determination that Defendant’s advertising is false “under accepted standards in the scientific and dietary supplement community.” (Opp’n at 9–10); see also Ocean Spray, 642 F. Supp. 2d at 1118; Pedimed, 419 F. Supp. 2d at 726; Mylan Labs. v. Matkari, 7 F.3d 1130, 1138 (4th Cir. 1993)

(Lanham Act claim could proceed because plaintiff alleged that defendant's statement regarding FDA-defined term was false); Sciele Pharma, slip op. at 11 ("Plaintiff notes in its complaint that the FDA has recognized D,L-MTHF as a different dietary ingredient than L-MTHF"). Plaintiffs' references to the FDA approval process serve, as Plaintiffs contend, "only as one source of evidence that, under accepted standards in the scientific and dietary supplement community, ProThera's labeling is false." (Opp'n at 9–10 ("[m]ere mention of [the NDI notifications] alone does not implicate the FDCA or FDA regulations"); see Compl. ¶ 35; see also Healthpoint Ltd. v. Straus Pharm., Inc., 273 F. Supp. 2d 871, 891–93 (W.D. Tex. 2001).

Lanham Act Claim

Section 43(a) of the Lanham Act prohibits any person from using in commerce "any word, term, [or] name . . . in commercial advertising or promotion [which] misrepresents the nature, characteristics, qualities, or geographic origin of his or her . . . goods." 15 U.S.C. § 1125(a).

Literal Falsity

Defendant argues, among other things, that "the ProThera ingredient labels are at a minimum subject to a true and correct interpretation and thus cannot be 'literally false.'" (Mot. at 21.) Plaintiffs respond that "the evidence demonstrates that the scientific community and dietary supplement industry consistently use[] and understand[] the term 'L-5-methyltetrahydrofolate' to mean the dietary ingredient that is the substantially pure isomer L-5-methyltetrahydrofolate, and not the different dietary ingredient, the . . . mixture D,L-5-methyltetrahydrofolate," found in Defendant's dietary supplements. (Pls.' Surreply at 4.)

Genuine issues of material fact exist regarding whether the use by Defendant of the term "L-5-methyltetrahydrofolate" to describe the product D,L-5-methyltetrahydrofolate is literally

false or whether, as Defendant claims, their labels are “subject to a true and correct interpretation.” See Johnson & Johnson v. GAC Int’l, Inc., 862 F.2d 975, 979–82 (2d Cir. 1988); see also Time Warner Cable, Inc. v. DIRECTV, Inc., 497 F.3d 144, 158 (2d Cir. 2007) (in evaluating literal falsity, a finder of fact “‘must analyze the message conveyed in full context’ If the words or images, considered in context, necessarily imply a false message, the advertisement is literally false[.]” (quoting Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 946 (3d Cir. 1993))); Avis Rent A Car System, Inc. v. Hertz Corp., 782 F.2d 381, 385 (2d Cir. 1986).

Plaintiffs adduce sufficient evidence for a reasonable jury to determine that “the name [L-5-MTHF] can be applied only to the pure or substantially pure” L-5-MTHF, and not to D,L-5-MTHF. (Opp’n at 22.) Defendant’s own witnesses – including proposed expert Dr. Claire Kruger, ProThera’s Chief Scientific Officer, Dr. Stephen Olmstead and ProThera’s Chief Executive Officer, Dr. Dennis Meiss – appear to agree that L-5-MTHF and D,L-5-MTHF are different. Dr. Kruger testified that “the L form [of MTHF] is chemically distinguishable from the mixture,” i.e., D,L-5-MTHF, (Kruger Tr. at 69:16-25), and that the terms “L-5-MTHF” and “D,L-5-MTHF” cannot be used interchangeably. (See Kruger Tr. at 58:9-12 (“Q. So when you discuss . . . L-5-MTHF, you are not referring to a diastereoisomeric mixture [i.e., D,L-5-MTHF]? A. No.”). Dr. Olmstead and Dr. Meiss both offer testimony in line with that offered by Dr. Kruger. (See Clayton Decl. Ex. 9 (Dep. of Stephen Olmstead, dated Dec. 11, 2008 (“Olmstead Tr.”)), at 118:1-25 (“Q. So what are the differences between those two products? [. . .] A. [O]bviously, one is primarily the racemic mixture of 5-methyltetrahydrofolate [i.e., D,L-5-MTHF] and the other is primarily the (6S) isomer of 5-methyltetrahydrofolate calcium salt [i.e., L-5-MTHF].”); Ex. 7 (Dep. of Dennis Meiss, dated Dec. 9, 2008 (“Meiss Tr.”)), at 336:2-15 (“Q. So I ask you again, do you believe that consumers may be misled into thinking the pure

isomers [i.e., L-5-MTHF] are used when, in fact, you are using a racemic version [i.e., D,L-5-MTHF]? A. That's what's expressed by myself in this e-mail."); see also Gregory Report ¶¶ 17, 51–53 (“[T]he Joint FAO/WHO Expert Committee on Food Additives concluded . . . [that] specifications for L-5-MTHF require <1% of the D isomer [i.e., D-5-MTHF].”); Clayton Decl. Ex. 13 (Joint FAO/WHO Expert Committee on Food Additives, “Compendium of Food Additive Specifications,” June 2005); Clayton Decl. Ex. 5 (Dep. of Dr. Jesse Gregory, dated May 6, 2009 (“Gregory Tr.”)), at 41:25–42:21, 214:4-12; Koch Tr. at 193:14-17.)³

Plaintiffs have adduced evidence upon which a jury could conclude that there is an appreciable and substantive difference between ingesting L-5-MTHF in its pure form and ingesting it as part of D,L-5-MTHF. That is, Defendant's (alleged) misrepresentations “concern an inherent quality or characteristic that is likely to influence purchasing decisions.”

Cumberland Packing Corp. v. Monsanto Co., 32 F. Supp. 2d 561, 582 (E.D.N.Y. 1999).

Plaintiffs' proposed expert, Dr. Jesse Gregory, concluded in his report, dated February 19, 2009, that D-5-MTHF “is nutritionally inactive as a source of folate but exhibits long retention in the body [and] can compete with [L-5-MTHF] and may suppress the role of L-5-MTHF[.] Because of the vital role of adequate folate nutrition[,], it is my opinion that the D isomer is not inert and that avoiding it is prudent.” (Gregory Report ¶ 68; see also id. ¶¶ 62–69.) Dr. Olmstead – Defendant's Chief Scientific Officer – testified that he was “aware of negative associations with D-isomers or racemic forms of [the] product,” such as D,L-5-MTHF. (Olmstead Tr. at 175:23–176:23.) Non-party witness Harold Koch, Jr. likewise testified about a study which “supports

³ “Diastereoisomeric” refers to the presence in the mixture of two different isomers (D-5-MTHF and L-5-MTHF) of 5-MTHF, while “racemic” refers to the fact that the two isomers are present in (nearly) equal quantities. (See generally Gregory Report ¶¶ 19–69.) The terms “(6S) isomer” and “L-isomer” (or “(6S)-5-MTHF” and “L-5-MTHF”) can be used interchangeably. (See Kruger Tr. at 57:13-23.)

that the inactive isomer [i.e., D-5-MTHF] is sequestered in the body, is not broken down, and does not leave the body.” (Koch Tr. at 276:8-12; see also Olmstead Tr. at 121:6-13 (“If I ordered the pure isomer [i.e., L-5-MTHF], then I would like to receive the pure isomer.”).)

Implicit Falsity

Defendant argues that Plaintiffs have “no survey or other extrinsic evidence to support any claim of ‘implicit falsity.’” (Mot. at 21.) Plaintiffs respond that “emails between ProThera and potential customers and testimony by one of ProThera’s fact witnesses . . . demonstrate[] that there was actual confusion as to what ingredient was included in ProThera’s product.” (Opp’n at 23 (emphasis omitted).) Plaintiffs argue, alternatively, that because ProThera “intentionally mislabeled its products, Merck is entitled to a presumption of deception and need not present any extrinsic evidence to establish” actual consumer confusion. (Pls.’ Surreply at 8–9 (emphasis omitted).)

To recover on a theory of implied falsity, a plaintiff must demonstrate “actual confusion” amongst consumers. This is usually done by adducing “extrinsic evidence,” such as consumer surveys, to show that the challenged advertisements “tend to mislead or confuse consumers.” Johnson & Johnson, 960 F.2d at 297–98. A plaintiff can also benefit from a presumption of “actual confusion” by adducing evidence that (1) defendant “has intentionally set out to deceive the public”; and (2) defendant’s “‘deliberate conduct’ in this regard is of an ‘egregious nature.’” Id. (quoting Res. Developers Co. v. Statue of Liberty-Ellis Island Found., Inc., 926 F.2d 134, 140 (2d Cir. 1991)). In such cases, “there is a presumption that consumers are being deceived and a plaintiff need not offer survey evidence.” Multivideo Labs, Inc. v. Intel Corp., No. 99 Civ. 3908, 2000 WL 12122, at *16 (S.D.N.Y. Jan. 7, 2000). Plaintiffs have raised a genuine issue of fact regarding “implicit falsity.”

With respect to “extrinsic evidence” of actual consumer confusion, Plaintiffs have not introduced a consumer survey but have adduced some (minimal) extrinsic evidence of consumer confusion. See Johnson & Johnson, 960 F.2d at 298; New Sensor Corp. v. CE Distribution LLC, 303 F. Supp. 2d 304, 316 (E.D.N.Y. 2004). Plaintiffs’ evidence shows that three consumers were (arguably) confused as to the nature of Defendant’s product. See Johnson & Johnson, 960 F.2d at 298 (plaintiff must establish “that a not insubstantial number of consumers’ hold the false belief allegedly communicated” (quoting Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317 (2d Cir. 1982) (emphasis added))). For example, in May 2008, an Italian pharmaceutical company inquired about purchasing L-5-MTHF from ProThera but did not go further after learning that ProThera offered only D,L-5-MTHF. (See Clayton Decl. Ex. 19.) In July 2008, the owner of a dietary supplement company inquired of ProThera about whether ProThera sold Merck’s trademarked Metafolin product – which is (nearly) pure L-5-MTHF. (See Clayton Decl. Ex. 20.) And, John Cranton, an executive of a company to which ProThera sold its folate products, testified that ProThera’s labeling of its folate products was misleading. (See Clayton Decl. Ex. 10 (Dep. of John A. Cranton, dated Oct. 17, 2008 (“Cranton Tr.”)), at 65:9–66:8.)

With respect to a presumption of actual consumer confusion, Plaintiffs adduce sufficient evidence for a jury to be able to find that Defendant “intentionally set out to deceive the public.” See Res. Developers, 926 F.2d at 140; Johnson & Johnson, 960 F.2d at 298. Plaintiffs’ allegation that Defendant, “knowing that it was . . . using an ingredient different from [L-5-MTHF], continued to label its products as using such,” (Pls.’ Surreply at 8), is arguably supported by Defendant’s own statements. (See Def. 56.1 ¶¶ 17–28 (“After ProThera resumed using [D,L-5-MTHF] in place of [L-5-MTHF], ProThera continued to state on its labels the

quantity of [L-5-MTHF] that was available in each tablet or capsule.”); Meiss Decl. ¶¶ 29–30; Ralston Decl. ¶ 14; Meiss Tr. at 335:10–336:15; Ralston Tr. at 231:25–233:18.) And, even though “the egregious standard is so high that the presumption is seldom if ever applied,” (Def.’s Surreply at 4), it is for a jury to determine whether the parameters of Defendant’s conduct was egregious. See M.V.B. Collision, Inc. v. Allstate Ins. Co., -- F. Supp. 2d --, No. 07 Civ. 187, 2010 WL 2985919, at *8 (E.D.N.Y. July 27, 2010) (“viewed in a light most favorable to [plaintiff], these incidents create an issue of fact as to whether [defendant’s] decisions . . . were egregious”); Fleary v. State of N.Y. Mortg. Agency, No. 04 Civ. 1557, 2006 WL 335701, at *11 (E.D.N.Y. Feb. 13, 2006) (“whether the conduct . . . was sufficiently egregious . . . raise[s] factual issues not appropriate for resolution on a summary judgment motion”); IMAF, S.p.A. v. J.C. Penney Co., No. 86 Civ. 9080, 1989 WL 54128, at *5 (S.D.N.Y. May 15, 1989) (“an issue of fact exists as to the . . . nature of defendant’s conduct”); see also Rexall Sundown, Inc. v. Perrigo Co., 651 F. Supp. 2d 9, 37–38 (E.D.N.Y. 2009); E-Z Bowz, L.L.C. v. Prof’l Prod. Research Co., No. 00 Civ. 8670, 2005 WL 535065, at *12 (S.D.N.Y. Mar. 8, 2005). The record reflects that Dr. Meiss wrote in an e-mail in October 2007: “We formulate our products so that the label declaration reflects the active isomer component. Thus, twice the amount of raw material is added to meet the . . . label[’s] claim. . . . There is a possibility that consumers may be mislead [sic] into thinking that the pure isomers [i.e., L-5-MTHF] are used.” (Clayton Decl. Ex. 8 (E-mail from Dennis Meiss to Rick Flora, dated Oct. 16, 2007).) Both Dr. Meiss and Janet Ralston stated that ProThera’s labels stated “the quantity of [L-5-MTHF] that was available,” even after ProThera had switched from using pure L-5-MTHF to using D,L-5-MTHF. (Meiss Decl. ¶ 29; Ralston Decl. ¶¶ 4 (“The content of the labels is determined by Dennis Meiss, our scientific advisor Stephen Olmstead, . . . and me.”), 11, 14.)

V. Conclusion

For the reasons stated herein, Defendant's motion for partial summary judgment [#69] is denied. The parties are directed to appear before the Court, with their principals, for a status/settlement conference on Tuesday, November 9, 2010, at 9:00 a.m., in Courtroom 21B of the United States Courthouse, 500 Pearl Street, New York, New York. **The parties are directed to work on settlement prior to the conference.**

Dated: New York, New York
October 20, 2010

A handwritten signature in black ink, consisting of the letters 'RMB' in a stylized, cursive-like font.

Richard M. Berman, U.S.D.J.